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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,241	06/20/2003	Donald L. Simmons	5600-84	6682

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,241	SIMMONS ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 12/27/07 is acknowledged. Any rejection that is not reiterated is hereby withdrawn.

Claims Pending

Claims 1, and 3-21 are pending. Claims 2, 22-30 are cancelled. Claims 1, and 3-21 are examined on the merits.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 3-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Anzaghi et al (US 2004/0166179), Jung (KR 2001096327), Yamawaki et al (US 4,696,929), as evidenced by Rochat et al (US 2004/0219157)*.

Anzaghi et al disclose a composition in drinkable solutions [0061] (liquid) for treating inflammation [0061] comprising 0.4-30% inulin, decaffeinated green tea dry extract, 50% in polyphenols at concentrations of 0.1%-2% (g/100 ml), blueberry dry extract (antioxidant), 25% in anthocyanidins (antioxidant), catechins and epicatechins (antioxidant) (see claim 9) and

vitamin C (antioxidant) (the same as ascorbic acid) at concentrations of 0.2-2% (g/100 ml) [0019]. Anzaghi et al also teach citric acid in the liquid compositions [0036]. Anzaghi et al further teach that the invention increases the solubility and absorption of the components [0013].

As evidenced by Rochat et al, inulin extract is commonly known as fructooligosaccharides [0027].

Anzaghi et al do not explicitly disclose the incorporation of fructooligosaccharides, citric acid, into their composition. Anzaghi et al do not a liquid composition being in a pH range of 4.7-5.0.

Jung discloses a drink (liquid) for treating inflammation comprising liquid fructooligosaccharide, vitamin C, and citric acid (see Abstract).

Yamawaki et al disclose a liquid preparation (col 5, lines 10-15) for treating inflammation (see Title). Yamawaki et al also teach that typical buffers include sodium citrate (col 5, lines 18-22), examples of pH-adjusting agents including citric acid etc, and stabilizers include EDTA (col 5, lines 25-30). Yamawaki et al further teach that the composition has excellent anti-inflammatory action (col 1, lines 28-33).

Rochat et al teach short chain fructooligosaccharide (it is inherent that it has a maximum degree of polymerization) [0047; 0048] for treating inflammation (see Title). Rochat et al also teach that the nutritional formula is preferably in the form of a liquid concentrate etc [0043].

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant compositions for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old composition of known properties where the results obtained thereby are no more than the additive effect of the compositions, *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Anzaghi et al, Jung, Yamawaki et al, and Rochat et al since all of them teach compositions for treating inflammation individually in the art. Since all the compositions yielded beneficial results treating inflammation, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the

limitation to the amount of the components or the pH of the composition, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on inflammatory condition or the stability of the composition that is needed.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Answer to Applicant's Argument

Applicant argues that since the present invention is useful for restoring and/or maintaining colon health. Therefore, it could not be said that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition to be used for the very same purpose (page 9, 3rd paragraph). Applicant's argument is not persuasive. Since the cited references are combined for the same purpose, namely, treating inflammation, the statement is correct. In addition, the intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use for restoring and/or maintaining colon health. It is deemed that the composition disclosed by cited references is not precluded for carrying out the intended function of the claims.

Applicant argues that the mere combination of a composition comprising fructooligosaccharides (FOS) with another comprising green tea catechin would result in a composition in which, depending on the pH of the composition, one of the two components would be degraded (page 10, 1st paragraph), and since FOS is stable in a neutral environment and green tea catechin is stable in an acidic environment, it cannot be said that it would have been obvious for a person skilled in the art to provide in an environment having a pH ranging from 4.7 to 5.0 that would allow both of these components to be stable within the same formulation (page 10, 3rd paragraph). In addition, Applicant argues that "FOS is stable in a neutral environment and green tea catechin is stable in an acidic environment".

Applicant's argument is not persuasive. First of all, although Anzaghi et al do not explicitly teach a composition comprising FOS, as evidenced by Rochat et al, inulin extract is commonly known as fructooligosaccharides, thus the drinkable solutions taught by Anzaghi et al comprising 0.4-30% inulin, decaffeinated green tea dry extract, 50% in polyphenols at concentrations of 0.1%-2% (g/100 ml), 25% in anthocyanidins (antioxidant), catechins and epicatechins inherently contains the claimed components FOS and green tea catechin in one composition. Although the reference is silent about pH, there is no reason to assume the invention of Anzaghi et al is unstable, or one of the two components would be degraded. Secondly, the secondary reference taught by Yamawaki et al discloses pH-adjusting agents including citric acid etc, and stabilizers include EDTA (col 5, lines 25-30). It is clear that prior art discloses adding citric acid to the beverage which would necessarily low the pH, and consequently change the taste of the beverage to suit individual preference. It is deemed that adjusting pH to an appropriate range is merely a matter of judicious selection and routine

optimization which is well within the purview of the skilled artisan. Further more, Applicant does not show any unexpected result about how crucial the claimed pH range is.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi

/Patricia Leith/

Primary Examiner, Art Unit 1655